MICRODEEP DEPTH ELECTRODE

AND ACCESSORIES

INSTRUCTIONS FOR USE

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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❒ Indication for use:

The DIXI Medical Microdeep Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.

❒ Description

The Microdeep Depth Electrodes are single patient use, sterile and disposable devices. The Microdeep Depth Electrodes are invasive as they are placed in contact with nerve tissue (brain) and must only be used during a sEEG procedure with Anchor Bolts. The Microdeep Depth Electrodes are intended to connect to the user's recording, monitoring and stimulation equipment using the Connection Systems. They are intended to be used only by physicians in the area of biopotential recording, monitoring and stimulation/response studies who are trained in the use of depth electrodes.

The Anchor bolt is available in 15mm, 20mm, 25mm, 30mm and 35mm lengths. The Microdeep Depth Electrode is available in 5 to 18 contacts, with an exploration length from 16 to 80.5mm.

The Microdeep Depth Electrodes and accessories are not made with natural rubber latex.

❒ Contraindications

The DIXI Medical Microdeep Depth Electrode and its accessories should not be used in the following cases:

- General contra-indications for any surgical operations (fever, angina, infection…);
- Infectious lesions to the scalp;
- Anticoagulant treatments;
- Presence of a CSF drainage system or an active CSF leak;
- Patients with a softening of the skull or low skull bone density.

❒ Warnings

⇨ DIXI Medical Microdeep Depth Electrode

The Microdeep Depth Electrode is not appropriate for use at a craniotomy site. This electrode must only be used with a DIXI Medical Anchor Bolt.

The Microdeep Depth Electrode should be introduced in an easy way and should not be forced.

The Microdeep Depth Electrode should be handled with extreme care to prevent damage. Patients with Microdeep Depth Electrodes in place must be kept under close observation. A direct pull on the Microdeep Depth Electrode may cause loss of contact recordings.

When the Microdeep Depth Electrode is not connected to DIXI Medical Connection Systems, the Microdeep Depth Electrode green connector must be protected by an appropriate bandage on the patient's head.

The Microdeep Depth Electrode is not intended for continuous stimulation. Stimulation should only be applied to support the brain mapping purpose of the electrodes.

The Microdeep Depth Electrodes must be disconnected from recording, monitoring and stimulation equipment during cardiac defibrillation.

The Microdeep Depth Electrode has not been proven to be magnetically compatible. Therefore, the Microdeep Depth Electrode must not be used in a MRI environment.

The Microdeep Depth Electrode is single use and intended for surgical use only. It is not intended for implantation (not for use ≥ 30 days).

⇨ DIXI Medical Anchor Bolt

The Anchor Bolt can only be used and placed through a small 2.1 mm hole drilled in the skull. The Anchor Bolt should be used only when depth electrodes are warranted.

The port hole of the Anchor Bolt is specially designed to accommodate the 0.8 mm Microdeep Depth Electrode. No other anchor bolt should be used in conjunction with the Microdeep Depth Electrode, or vice versa.

The cap of the Microdeep Depth Electrode must be screwed on the Anchor Bolt to stabilize the Microdeep Depth Electrode during electroclinical characterizations.

The Anchor Bolt has not been proven to be magnetically compatible. Therefore, the Anchor Bolt must not be used in a MRI environment.

The Anchor Bolt is single use and intended for surgical use only. It is not intended for implantation (not for use ≥ 30 days).

⇨ Other DIXI Medical accessories for DIXI Medical Anchor Bolt and DIXI Medical Microdeep Depth Electrode placement

DIXI Medical has developed a full range of accessories allowing the anchorage of Anchor Bolts in the skull and the placement of Microdeep Depth Electrode in the brain. No other accessories should be used in conjunction with these Anchor Bolts and Microdeep Depth Electrodes, or vice versa.

The accessories used to place the Anchor Bolt in the skull (Bone Starter, Drill, Coagulation Electrode, Long Screwdriver and Marking Rod) must be used through a stereotactic guidance system with an internal diameter of 2.5mm. When using the Drill, this guidance system must be placed as closed as possible to the skin to prevent axial deviation.

When using the Drill, appropriate cooling is necessary to aid the prevention of thermal injury to bone tissue. It should be combined with low speed drilling to prevent any risk of possible loosening of the Anchor Bolt due to bone demineralization and injury to the patient.

The Coagulation Electrode use requires a ground pad fixed to the patient and the application of the high frequency current inside the Coagulation Electrode must be done only once the Coagulation Electrode is in contact with the skin or the Dura. The Coagulation Electrode must be handled using the plastic hand during the application of high frequency electrical current (this current should not exceed 47mA, corresponding to a power of 224W, during a few seconds).

The accessories used for Anchor Bolt and Microdeep Depth Electrode placement are made of materials that must not be used in a MRI environment.

The accessories that have direct contact with the central nervous system (Coagulation Electrode and Stop, Drill and Stop and Stylet) are single use. The accessories that have no contact with the central nervous system (Instrument Guide, Bone Starter, Sliding Ruler, Flat Screwdriver for Stop, Long Screwdriver, Marking Rod, Cap for Anchor Bolt, Depth Report Device, Wrench and Short Screwdriver) must be steam sterilized before use. All these accessories are intented for surgical use only.

⇨ DIXI Medical Connection Systems

The Connection Systems (Extension Cable, Adapter and Connection Cable) are specially designed to connect the Microdeep Depth Electrodes from the patient to the user's recording, monitoring and stimulation equipment. They are only intended to transmit the electrical energy between the user's recording, monitoring and stimulation equipment and the Microdeep Depth Electrode. No other connection systems should be used to connect Microdeep Depth Electrode and no other depth electrode should be connected to Connection Systems.

The Connection Systems must not be dismantled.

The Connection Systems are made of materials that must not be used in a MRI environment

The Connection Systems have no contact with the patient. According to the pratician's need, Extension Cables and Connection Cables can be steam sterilized before use. Adapters must not be steam sterilized.

❒ Use

⇨ Application

The placement of the Microdeep Depth Electrode requires a stereotactic equipment (frame or robot) and a neurosurgical procedure that should be performed by a trained neurosurgeon.

The recording and stimulation of electrical signals should be performed by a trained electrophysiological neurologist.

The removal of Microdeep Depth Electrode should be performed by a trained neurosurgeon.

⇨ Microdeep Depth Electrode placement procedure

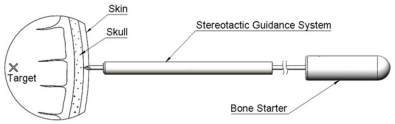
The procedure requires a precise planning for the depth electrodes placement. The Microdeep Depth Electrodes must be placed with the use of conventional stereotactic technique (stereotactic frame) or with the assistance of stereotactic robotic devices. The planning of the electrodes implantation must be confirmed and optimized by appropriate medical imaging.

Prior to the placement of electrodes, the stereotactic guidance system must be adjusted in the planned trajectory (it is possible to use an Instrument Guide). The placement procedure of each Microdeep Depth Electrode is as follows:

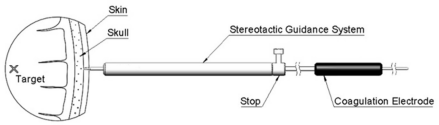
Placement of the Anchor Bolt

Note: all steps required for the placement of the Anchor Bolt are performed through the stereotactic guidance system.

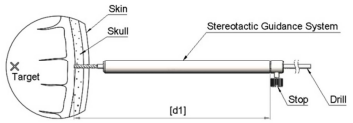
- Make a small incision in the skin and mark the skull using the Bone Starter.



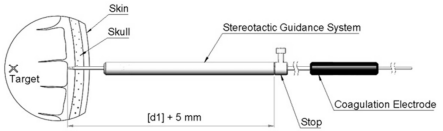
- Coagulate the skin using the Coagulation Electrode.



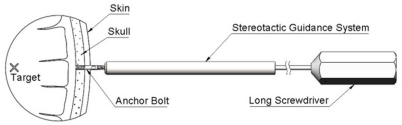
- Drill the patient's skull using a Drill with a cutting diameter of 2.1mm and fitted with the Stop (move the stop back in gradual steps until the skull's inner cortex is reached).



- After removing the Drill, measure the distance [d1] between the Drill tip and its Stop using the Sliding Ruler. This distance, corresponding to the distance between the skull inner cortex and the stereotactic guidance system, will act as a reference when checking the insertion length of the Coagulation Electrode.
- Accurately position the Stop of the Coagulation Electrode using the Sliding Ruler: the Stop position is calculated by adding to the distance obtained from the Drill insertion [d1] a sufficient distance to open the Dura (about 5mm).
- Open the Dura using the Coagulation Electrode.

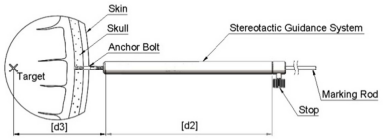


- Screw the Anchor Bolt into the patient's skull using the Long Screwdriver.
  Note: a Cap for Anchor Bolt can be used to avoid cerebrospinal fluid leakage before the placement of the Microdeep Depth Electrode.

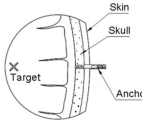


Placement of the Microdeep Depth Electrode

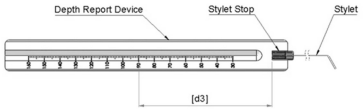
- Measure the distance [d2] between the external tip of the Anchor Bolt and the stereotactic guidance system using the Marking Rod with the Stop and the Sliding Ruler.



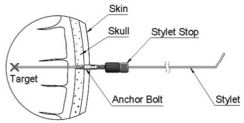
- Calculate the distance [d3] between the external tip of the Anchor Bolt and the target by taking the distance [d2] away from the known distance between the stereotactic guidance system and the target.
- Remove the stereotactic guidance system.



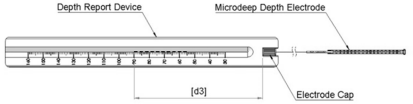
- Report the distance [d3] on the Stylet using the Depth Report Device.



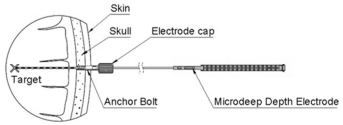
- Slowly and carefully insert the Stylet into the brain through the Anchor Bolt until the Stylet stop touches the external tip of the Anchor Bolt.



- Report the distance [d3] on the Microdeep Depth Electrode using the Depth Report Device.



- Remove the Stylet once the Microdeep Depth Electrode is ready to be implanted.
- Slowly and carefully insert the Microdeep Depth Electrode into the brain through the Anchor Bolt until the Electrode cap touches the Anchor Bolt.
- Screw the Electrode cap onto the Anchor Bolt without over-tightening.



⇨ **Microdeep Depth Electrode connection**

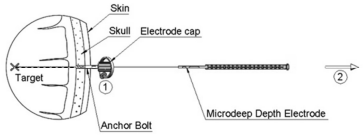
The Microdeep Depth Electrode should only be connected to recording, monitoring and stimulation equipment that is specifically designed for stereo-electroencephalography (SEEG) exploration and which complies with applicable safety requirements.

To accommodate physician's preference, two solutions are available to connect the Microdeep Depth Electrode to the recording, monitoring and stimulation equipment:

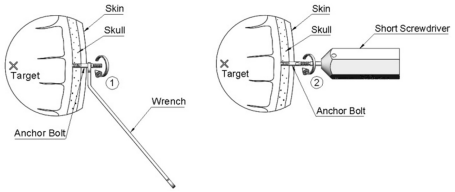
- The Extension Cable is used to connect the Microdeep Depth Electrode to the Adapter, and the Adapter allows to connect the Extension Cable to a fixed headbox that is itself connected to the recording, monitoring and stimulation equipment.
- The Connection Cable is used to connect the Microdeep Depth Electrode directly to a headbox tied to the patient. This headbox is linked to the recording, monitoring and stimulation equipment

⇨ **Microdeep Depth Electrode removal procedure**

- Unscrew the cap on the Microdeep Depth Electrode and slowly and carefully remove the Microdeep Depth Electrode.



- To remove the Anchor Bolt, firstly use the Wrench on the two flat points on the Anchor Bolt to loosen the bolt. Once loose, use the Short Screwdriver to finish the removal of the Anchor Bolt.



- Suture the skin.

⇨ **Microdeep Depth Electrode and accessories disposal**

The Microdeep Depth Electrodes and accessories are not recyclable and must be integrated to the standard treatment of contaminated products in hospitals.

❒ Complications

The use of Microdeep Depth Electrodes and accessories can be associated with the following complications:

- The surgical procedure involving the placement of Anchor Bolts and Microdeep Depth Electrodes may cause haemorrhaging and/or infection complications along the electrode path, neurologic deficits, headaches, hydrocephalus, cerebral infarctions, cerebral edemas, CSF leakage or electrode ruptures or accidental removals during epileptic seizure.
- The use of the Drill might cause skin injuries, thermal injuries to bone tissue, bone demineralisation, skin and/or skull infections or perforation of nerve tissue.
- The use of the Coagulation Electrode might cause burns or alterations of brain tissue.

❒ Cleaning, sterilization, shelf life and storage

⇨ **Microdeep Depth Electrode, Anchor Bolt, Stylet, Drill, Coagulation Electrode and Cap for Anchor Bolts**

The Microdeep Depth Electrodes, Anchor Bolts, Stylets, Drills, Coagulation Electrodes and Caps for Anchor Bolts are **for single use only** and are provided **sterile** (sterilization by ethylene oxide). They must be used before the expiration date indicated on the packaging.

DIXI Medical can not guarantee the level of contamination after use, the effectiveness of any re-sterilization procedure, nor the functionality of the device in case of re-use. As a result, **re-sterilization and re-use are forbidden.**

The packaging of each Microdeep Depth Electrode, Anchor Bolt, Stylet, Drill, Coagulation Electrode or Cap for Anchor Bolts must be inspected for any damage before use. **The device must not be used if the package is damaged.**

The Microdeep Depth Electrodes, Anchor Bolts, Stylets, Drills, Coagulation Electrodes and Caps for Anchor Bolts must be stored in theirs original packaging, protected from shocks, in a dry and cool place.

⇨ **Instrument Guide, Bone Starter, Sliding Ruler, Flat Screwdriver for Stop, Long screwdriver, Marking Rod, Depth Report Device, Wrench and Short Screwdriver and, if used in a sterile environment, Extension Cable and Connection Cable**

These accessories are non sterile and reusable accessories to be used with the Microdeep Depth Electrode.

Before the first use, the reusable accessories have to be cleaned, inspected and sterilized according to the instructions described in the paragraphs "Cleaning", "Inspection" and "Sterilization" below.

Between each use, the reusable accessories must be pre-cleaned, cleaned, inspected and sterilized according to the instructions described in the paragraphs "Pre-cleaning", "Cleaning", "Inspection" and "Sterilization" below.

Caution:
The accessories do not need to be disassembled before cleaning and sterilization.
Abrasives cleaning tools (e.g. metal brushes) must never be used for the pre-cleaning or the cleaning.
The quality of water used for diluting cleaning and/or disinfectants and for rinsing accessories should be carefully considered. Use highly purified or sterile water for final rinsing.
It is the responsibility of the user to ensure that the reprocessing of the accessories is performed following this procedure, using qualified equipment, material and personnel.

Pre-cleaning (in case of reuse, at the point of use)

1. Within the 30 minutes following use, soak the accessory in a neutral pH enzymatic detergent as per the manufacturer's instructions. Ensure that the accessory is completely immersed.
   When validating these instructions, DIXI Medical used a 0.5% dilute solution of ANIOSYME DD1 for 5 minutes at room temperature (approximately 20°C). ANIOSYME DD1 is aldehyde and chlorine free, with a neutral pH, supplied by ANIOS for pre-disinfection and cleaning of instrumentation.
2. Remove any visible soil by lightly brushing the accessory with suitable brushes (only soft plastic brushes). Pay particular attention to all the areas where the soil could be imbedded.
3. Rinse the accessory with tap water.
4. Visually inspect the accessory for any remaining soil (pay particular attention to lumens, slots…) and repeat the steps above if necessary.
5. Dry the device with a clean paper towel or lint-free pad.

Cleaning

Two solutions may be used for the cleaning: manual cleaning or automated cleaning using washer disinfector.

Manual cleaning:

1. Soak the accessory in a neutral pH enzymatic detergent as per the manufacturer's instructions. Ensure that the accessory is completely immersed.
   When validating these instructions, DIXI Medical used a 0.5% dilute solution of ANIOSYME DD1 for 5 minutes at room temperature (approximately 20°C). ANIOSYME DD1 is aldehyde and chlorine free, with a neutral pH, supplied by ANIOS for pre-disinfection and cleaning of instrumentation.
2. Remove any visible soil by lightly brushing the accessory with suitable brushes (only soft plastic brushes). Pay particular attention to all the areas where the soil could be imbedded.
3. Rinse the accessory with tap water.
4. Soak the accessory in a disinfectant solution as per the manufacturer's instructions. Ensure that the accessory is completely immersed.
   When validating these instructions, DIXI Medical used an undiluted solution of ACTANIOS HLD for 30 minutes at room temperature (approximately 20°C). ACTANIOS HLD is aldehyde and chlorine free, with an acid pH, supplied by ANIOS for high level disinfection of instrumentation.
5. Lightly brush the accessory with suitable brushes (only soft plastic brushes). Pay particular attention to all the areas where the soil could be imbedded.
6. Rinse the accessory using highly purified or sterile water.
7. Dry the device with clean and lint-free single use wipes.
8. Visually inspect the accessory under good light conditions for any remaining soil (pay particular attention to lumens, slots…) and repeat the steps above if necessary.

Automated cleaning (recommended):

A cleaning cycle should be performed in a washer-disinfector with FDA approval in accordance with ISO 15883, properly installed, qualified and regularly subjected to maintenance and testing. The following steps should be completed in sequence:

1. Soak the accessory in a neutral pH enzymatic detergent as per the manufacturer's instructions. Ensure that the accessory is completely immersed.
   When validating these instructions, DIXI Medical used a 0.5% dilute solution of ANIOSYME DD1 for 5 minutes at room temperature (approximately 20°C). ANIOSYME DD1 is aldehyde and chlorine free, with a neutral pH, supplied by ANIOS for pre-disinfection and cleaning of instrumentation.
2. Remove any visible soil by lightly brushing the accessory with suitable brushes (only soft plastic brushes). Pay particular attention to all the areas where the soil could be imbedded.
3. Rinse the accessory with tap water.
4. Place the accessory in the automatic washer-disinfector and run a cleaning cycle. Solutions used should be prepared and used in accordance with the manufacturer's instructions.
   When validating these instructions, DIXI Medical used for cleaning a 1% diluted solution of ACTANIOS LDI for 10 minutes at 55°C. ACTANIOS LDI is a basic detergent supplied by ANIOS for detergence and disinfection of instrumentation in automatic washing machine.
5. If necessary, remove remaining wetness with clean and lint-free single use wipes.
6. Visually inspect the accessory under good light conditions for any remaining soil (pay particular attention to lumens, slots…) and repeat the steps above if necessary.

Inspection and wrapping

After cleaning and before preparing for sterilization, the accessory should be inspected.
A visual inspection under good lighting conditions and a functional check should be performed: the accessory should be checked for corrosion and/or damage or wear. Pay particular to moving parts, markings and sharpness of cutting tips.

If the accessory conforms, the accessory must be wrapped in suitable sterilization wraps for the steam sterilization process. Wraps used for sterilization should be FDA-cleared and the accessory should be **double wrapped** according to the AAMI ST79 method or equivalent.

Caution: DIXI Medical does not define the maximum number of use appropriate for re-usable medical devices. The useful life of these devices depends on many factors including the method and duration of each use and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life for the accessory. The accessory should be replaced in case of doubt concerning its integrity or function.

Sterilization

In accordance with DIXI Medical validation, the sterilization parameters are the following:

PRE-VACUUM AUTOCLAVE CYCLE	
Temperature	132°C
Exposure Time	4 minutes
Drying Time	30 minutes (in autoclave) 15 minutes (open door)
Cool Down	30 minutes (outside of autoclave)

Caution: autoclave design and performance can affect the efficacy of the process. Healthcare facilities should validate the process that they use, for different sterilization chambers, packaging methods and/or various load configurations. Autoclaves should be FDA-cleared and properly installed, validated, maintained and checked.Other steam sterilization cycles may also be suitable but the hospitals are advised to validate them.

Between each use, the steam sterilized reusable accessories must be stored in the sterilization wraps at room temperature, in a dry place, protected from physical impacts and sun light. Prior to use, each steam sterilized reusable accessory should be inspected for integrity. If a package is suspect, the accessory should not be used and the accessory should be reprocessed.

⇨ **DIXI Medical Connection Systems**

The Connection Systems are non sterile and reusable accessories of the Microdeep Depth Electrode. Adapters must not be sterilized.

Caution:
According to the user's need (use in a sterile environment), Extension Cables and Connection Cables can be cleaned and steam sterilized before use according to the procedure described in the above paragraph.
For the cleaning procedure described below, the Connection Systems should not to be disassembled and should not be immersed in the cleaning solution.

The Connection Systems should be cleaned before each use as follow:

- Scrub the Connection System using a compress soaked with a detergent solution prepared per the manufacturer's instructions.
- Remove the detergent solution using a compress soaked with mains water.
- Dry the Connection System using a clean and lint-free wipe.
- Visually inspect the Connection System for potential remaining soil and damage or wear and check the Connection System for functionality. The Connection System should be replaced in case of doubt concerning its functioning or its integrity.

Between each use, the Connection Systems must be stored at room temperature, in a dry place, protected from physical impacts and sun light.

❒ Symbols guide

REF	Catalogue number
LOT	Batch number
	Single-use item, do not reuse
STERILE EO	Sterilized using ethylene oxide
	Use by
	Caution
SN	Serial number
	Consult Instructions for use
	Manufacturer
	Store in a dry place
	Do not resterilize
	Keep away from sunlight
	Do not use if the packaging is damaged
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

❒ Limited replacement warranty and liability

DIXI Medical guarantees that the Microdeep Depth Electrode and its sterile delivered accessories conform to requirements when used within the expiration date indicated on the packaging. DIXI Medical also guarantees that the non-sterile delivered accessories conform to requirements.
Items may not be returned without the prior approval of DIXI Medical (returned Depth Electrodes or accessories are to be sent for inspection in appropriate packaging and include a detailed description of the defect). The warranty expressly excludes faults or defects resulting in part or in full from failure to comply with the storage conditions or from improper use.
No other warranty is given, whether expressly or implicitly, beyond the limited replacement warranty. DIXI Medical declines all responsibility with regard to any other undertaking offered in its name in respect of the product and prohibits anyone from offering any other such undertaking.

DIXI Medical declines all responsibility for any direct or consequential damage relating to the use of these products such as:
- external causes not linked to products supplied by DIXI Medical or causes which are beyond its control.
- use of the product in a manner that does not strictly comply with the recommendations, instructions or warnings given previously herein. Thus, in particular, any infection of the patient related to the reuse and/or re-sterilization of sterile and single use delivered device must not, in any case, be imputable to DIXI Medical.